

September 16, 1999



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Dockets Management Branch (HFA-305) 3268  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

SEP 17 1999 14:14

RE: Docket No. 99N-1307

Dear Sir or Madam:

I offer the following comments related to the proposed rule cited in this docket:

The Proposal to Require Refrigeration of Shell Eggs in  
Retail Establishments

We have no problems with this provision provided it is enforced using good judgement. It would be highly inappropriate to order the destruction or diversion of eggs found stored in an establishment environment which was a few degrees above the specified but arbitrary 45F. Depending upon the SE status of the source flock and the age of the eggs, they could be perfectly safe for human consumption even though held at temperatures slightly greater than 45F. In other words, there are no data to show that 45F is satisfactory and 48F is unsatisfactory as a storage temperature requirement for eggs. That temperature (45F) was subjectively decided upon as the mandated egg storage temperature because colder temperatures were generally known to be better for food storage than warmer temperatures.

The Proposal for Shell Egg Labeling

We find the proposed wording of the label to be too long, too detailed and too alarming. Such a label will frighten consumers who are not familiar with the extremely low level of risk from the home use of shell eggs and will unjustifiably result in reduced egg sales, harming a depressed industry. Worse yet, mothers will likely read **the** label and decline to purchase eggs that their growing children need as part of a healthy diet.

A simple label that delivers the message "refrigerate and cook well" will be adequate to accomplish your purpose. "Scare" labels on alcohol and tobacco have little beneficial effect because of the addictive nature of these products. Such labels on eggs, however, will absolutely have a negative impact on egg sales, probably irreversibly. We do not believe such a tactic is appropriate, especially as the incidence of human illnesses due to S. enteritidis (SE) has declined markedly (44%) based on your FoodNet data.

99N-1307

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The proposed rule exempts shell eggs that have been "processed" to destroy Salmonella (pasteurized) from the labeling requirement. That exemption is obviously made because such eggs are not likely to contain SE. Eggs that are produced by flocks tested and found **to be** environmentally negative for SE are also highly unlikely to contain SE. Therefore, **eggs from** SE-negative flocks should also be exempt from the labeling requirement. Such an exemption would provide an incentive for producers to enroll and comply with Egg Quality Assurance Programs that include testing because labeled eggs will not sell as well as unlabeled eggs. Consumers will believe the label is justified by an appropriate level of hazard and will elect not to buy labeled eggs.

In summary, the refrigeration provision must be enforced with good judgement, realizing that the 45F requirement was based on the long-held belief that refrigeration was good for food and not **based** on scientific comparison between 45F and **48F**, for example. Neither has it been demonstrated that such refrigeration will decrease human illnesses due to SE. The proposed labeling rule is entirely inappropriate based on the declining incidence of SE human illnesses. It is unlikely to have any positive effect on reducing human illness due to the consumption of eggs and would be best set aside. It will have an impact but it will be to decrease the use of eggs in the diets of those who need them the most and not to decrease human illness.

Lastly, we have to be concerned about eggs being the food item selected for such alarming labels when the USDA risk assessment report you cite predicts that only 1 in 20,000 eggs will contain any SE at all. You cite another report that states on average, each person consumed undercooked eggs 20 times a year. If an individual ate an egg each day, it means that they are likely to eat one contaminated egg in 55 years. If they also ate 20 undercooked eggs during each year, the likelihood of the one egg in 55 years being one that is not only contaminated but undercooked is too remote to warrant discussion.

Thank you for the opportunity to comment on this proposed regulation before it is finalized as a rule.

Sincerely,



C. W. BEARD, D.V.M., Ph.D.  
Vice President, Research and Technology  
[cbeard@poultryegg.org](mailto:cbeard@poultryegg.org)

CWB:jl

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**Company** US POULTRY & EGG

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**City** TUCKER **State** GA **ZIP** 30084

**2 Your Internal Billing Reference Information**

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**Recipient's name** Federal Drug Administration

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